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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/926,571	11/28/2001	Richard A Dixon	11137/04808	8964
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Eugenia S Hansen Sidley Austin Brown & Wood 717 N Harwood Suite 3400 Dallas, TX 75201			EXAMINER KALLIS, RUSSELL	
			ART UNIT 1638	PAPER NUMBER

DATE MAILED: 02/04/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/926,571

Applicant(s)

DIXON ET AL.

Examiner

Russell Kallis

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 30 October 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-50 is/are pending in the application.
- 4a) Of the above claim(s) 15-35, 39-42 and 47-50 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-14, 36-38 and 43-46 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 20 November 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.  
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4/12/2002. 6) ☐ Other:

## **DETAILED ACTION**

### ***Election/Restrictions***

Applicant's election without traverse of Group I, Claims 1-14, 36-38 and 43-46 in Paper No. 10/30/2003 is acknowledged.

Claims 1-50 are pending. Claims 1-14, 36-38 and 43-46 are examined. Claims 15-35, 39-42 and 47-50 are withdrawn.

### ***Priority***

An application in which the benefits of an earlier application are desired must contain a specific reference to the prior application(s) in the first sentence of the specification of in an application data sheet (37 CFR 1.78(a)(2) and (a)(5)). The specific reference to any prior nonprovisional application must include the relationship (i.e., continuation, divisional, or continuation-in-part) between the applications except when the reference is to a prior application of a CPA assigned the same application number. This application is a 371 of PCT/US00/13389 filed 05/15/2000 that claims priority to U.S. provisional application 60/136,026 filed 05/20/1999. Appropriate correction is required.

### ***Claim Objections***

Claim 36, line 1 is objected to because of the following informalities: The use of "by" does not clearly set forth the method step. Substituting --comprising-- will overcome this objection. Appropriate correction is required.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-14, 36-38 and 43-46 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant broadly claims an isolated DNA fragment comprising an isoflavone *O*-methyltransferase gene; a DNA fragment that hybridizes to SEQ ID NO: 1 under conditions of moderate stringency; other necessary enzymes of isoflavonoid biosynthesis; and a recombinant DNA sequence encoding a portion of an isoflavone *O*-methyltransferase gene that increases the level of at least one or produces at least one 4' *O*-methylated isoflavonoid compound in a transformed plant.

Applicant describes SEQ ID NO: 1.

Applicant does not describe an isolated DNA fragment or a recombinant DNA sequence encoding a full length or a portion of a 4-*O*-methyltransferase gene other than SEQ ID NO: 1.

The Federal Circuit has recently clarified the application of the written description requirement to inventions in the field of biotechnology. The court stated that, "A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or of a recitation

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of structural features common to members of the genus, which features constitute a substantial portion of the genus.” See *University of California v. Eli Lilly and Co.*, 119 F.3d 1559; 43 USPQ2d 1398, 1406 (Fed. Cir. 1997).

Applicants fail to describe a representative number of isolated DNA fragments or a recombinant DNA sequence encoding a full length or a portion of a 4-*O*-methyltransferase gene. Applicants only describe a single cDNA (SEQ ID NO:1). Furthermore, Applicants fail to describe structural features common to members of the claimed genus of polynucleotides. Hence, Applicants fail to meet either prong of the two-prong test set forth by *Eli Lilly*. Furthermore, given the lack of description of the necessary elements essential for isoflavone *O*-methyltransferase activity, it remains unclear what features identify a isoflavone *O*-methyltransferase encoding polynucleotide. Since the genus of DNA fragments or a recombinant DNA sequence encoding a full length or a portion of a 4-*O*-methyltransferase encoding polynucleotide has not been described by specific structural features, the specification fails to provide an adequate written description to support the breadth of the claims.

Sequences that hybridize with SEQ ID NO: 1, under conditions of moderate stringency, encompass naturally occurring allelic variants, mutants of isoflavone *O*-methyltransferase encoding polynucleotides, as well as sequences encoding proteins having no known isoflavone *O*-methyltransferase activity, of which Applicant is not in possession. Accordingly, the specification fails to provide an adequate written description to support the genus of polynucleotides encompassed by the hybridization language as set forth in the claims. (See Written Description guidelines published in Federal Register/Vol. 66, No.4/Friday, January 5, 2001/Notices: p.1099-1111).

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Claims 1-14, 36-38 and 43-46 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method increasing disease resistance and of increasing native levels of at least one 4' *O*-methylated isoflavonoid compound in a leguminous plant that natively produces 4' *O*-methylated isoflavonoids by expressing an isoflavone *O*-methyltransferase gene of SEQ ID NO: 1, does not reasonably provide enablement for a method of increasing disease resistance and increasing levels of 4' *O*-methylated isoflavonoids in any plant that natively produces 4' *O*-methylated isoflavonoids by transformation using any isoflavone *O*-methyltransferase gene, or with a DNA fragment that hybridizes to SEQ ID NO: 1 under conditions of moderate stringency other than SEQ ID NO: 1; or for producing 4' *O*-methylated isoflavonoids by transformation of a non 4' *O*-methylated isoflavonoid producing plant using any isoflavone *O*-methyltransferase gene in combination with any number of DNA sequences encoding enzymes necessary for isoflavonoid biosynthesis. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

Applicant broadly claims methods of increasing disease resistance and of increasing levels of at least one 4' *O*-methylated isoflavonoid compound in a plant that natively produces 4' *O*-methylated isoflavonoids by expressing an isoflavone *O*-methyltransferase gene, or by expressing a DNA fragment that hybridizes to SEQ ID NO: 1 under conditions of moderate stringency; or by expressing a recombinant DNA sequence encoding a portion of an isoflavone *O*-methyltransferase gene; and a method of producing at least one 4' *O*-methylated isoflavonoid compound in a plant that does not produce 4' *O*-methylated isoflavonoid compounds by

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transformation with any isoflavone *O*-methyltransferase gene in combination with any number of the other necessary enzymes of isoflavonoid biosynthesis.

Applicant teaches a method of increasing disease resistance and of increasing levels of 4' *O*-methylated isoflavonoid compounds in alfalfa transformed with SEQ ID NO: 1 (Examples 1-4, pages 13-18 and page 21, lines 5-23).

Applicant does not teach a method of increasing disease resistance or of increasing levels of 4' *O*-methylated isoflavonoid compounds in any plant by transformation using any isoflavonone *O*-methyltransferase gene; or a method of producing 4' *O*-methylated isoflavonoid compounds in any plant by transformation using any isoflavonone *O*-methyltransferase gene in combination with any number of the other necessary enzymes of isoflavonoid biosynthesis.

The isolation of orthologous DNA sequences from other species introduces an element of unpredictability. The limitation is introduced in finding homologous regions that would adequately enable either PCR amplification or southern hybridization and would entail using either degenerate primers or probes with limited sequence identity. Thus the screen for orthologous sequences would isolate many genes other than those of interest. The inherent unpredictability in isolation of a homologous sequence encoding the same protein activity is illustrated in an example where a small number of changes to the coding region for a strict desaturase resulted in an enzyme with a hydroxylase activity and that a small number of changes to the coding region of a desaturase could account for the functional divergence seen across a range of enzymes involved in fatty acid metabolism (Broun P. *et al.* Science Vol. 282; 13 November 1998, pp. 1315-1317; Abstract lines 4-6 and p. 1317 column 1, lines 37-56).

Further, the engineering of a metabolic process such as the production of 4' *O*-methylated isoflavonoid compounds in a plant where no production of 4' *O*-methylated isoflavonoid compounds has ever been detected would require an understanding of the complex regulation of the multi-enzymatic complex such that one of skill in the art resort to undue trial and error experimentation testing any number of non-exemplified combinations of the other necessary enzymes for isoflavonoid biosynthesis in a multitude of non-exemplified plants species that do not produce natively 4' *O*-methylated isoflavonoid compounds and most likely do not produce the necessary precursors required for the end product (Dixon R. *et al.* Flavonoids in the living systems, ed. Manthey and Buslig; Plenum Press, New York 1998, pages 55-66; page 63, see future prospects).

Given the unpredictability in the art as to which isolated polynucleotides would encode an isoflavone *O*-methyltransferase gene; the breadth of the claims encompassing methods increasing disease resistance and of increasing levels of at least one 4' *O*-methylated isoflavonoid compound in a plant that natively produces 4' *O*-methylated isoflavonoids by expressing an isoflavone *O*-methyltransferase gene, or by expressing a DNA fragment that hybridizes to SEQ ID NO: 1 under conditions of moderate stringency; or by expressing a recombinant DNA sequence encoding a portion of an isoflavone *O*-methyltransferase gene; and a method of producing at least one 4' *O*-methylated isoflavonoid compound in a plant that does not produce 4' *O*-methylated isoflavonoid compounds by transformation with any isoflavone *O*-methyltransferase gene in combination with any number of the other necessary enzymes of isoflavonoid biosynthesis; the lack of guidance in the examples of the specification or in the prior art as to which non-exemplified DNA sequences would when transformed into a plant



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would either increase levels of or produce 4' *O*-methylated isoflavonoids one would not know based upon Applicant's disclosure which embodiments would be inoperable and predictably eliminated, and thus undue trial and error experimentation would be needed by one skilled in the art to make and clone a multitude of non-exemplified 4' *O*-methylated isoflavonoid biosynthetic enzymes and would require one of skill in the art to test in a myriad of non-exemplified plants for increased production or production of 4' *O*-methylated isoflavonoids in non-exemplified transformed plant species. Therefore, the invention is not enabled for the scope set forth in the claims.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 5, 12, 14, 38 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

***Claim Rejections - 35 USC § 101***

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 44-46 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The claims are drawn to seeds or progeny of transgenic plants encompassing untransformed plants and seeds, which are a product of nature and not one of the five classes of patentable subject matter. Due to Mendelian inheritance of genes, a single gene introduced into a parent plant would only be transferred at most to half the male gametes and

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half the female gametes. This translates into only two thirds of the progeny having at least a single copy of the transgene and one quarter of the progeny would not carry a copy of the transgene. Since the claim encompasses progeny that lack the transgene, the claim encompasses plants and seeds that are indistinguishable from plants and seeds that would occur in nature. See *American Wood v. Fiber Distintegrating Co.*, 90 U.S. 566 (1974), *American Fruit Growers v. Brogdex Co.*, 283 U.S. 2 (1931), *Funk Brothers Seed Co. v. Kalo Inoculant Co.*, 33 U.S. 127 (1948), *Diamond v. Chakrabarty*, 206 USPQ 193 (1980).

All claims are rejected.

Claims 1-14, 36-38 and 43-46 are deemed free of the prior art, given the failure of the prior art to teach or reasonably suggest methods for producing and increasing the production of 4'-O-methylated isoflavonoid compounds in a plant transformed with an isoflavone O-methyltransferase gene and transgenic plants thereof.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Russell Kallis whose telephone number is (571) 272-0798. The examiner can normally be reached on M-F 8:30-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on (571) 272-0804. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0198.

Russell Kallis Ph.D.  
January 21, 2004



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